

**DO NOT SUBMIT THIS PAGE TO HSD**

**PURPOSE**

Use this form to request modifications to an already approved IRB application, provide new information, add or remove research team members in specific roles, and safety monitor or DSMB reports. Use the [REPORT CHANGE: Confidentiality Agreement, Personnel](#) form instead of this form if the only change you are making is to add or remove names from an existing Confidentiality Agreement.

**INSTRUCTIONS**

- Please see the SOP Modifications for more information.
- When preparing double-sided copies, please make sure that each item (e.g. Modification Form, consent forms, study instruments, etc. ) begins on the front of a new piece of paper.
- We will not accept handwritten forms.
- NUMBER OF COMPLETE PACKETS: Three(3). (Two packets for minimal risk).
- For users of the UW Clinical Research Center (CRC) in the UW Medical Center of 7 South: modifications that impact resource utilization on the CRC MUST ALSO be submitted to ITHS for review and approval prior to implementation. Email to: [iths-crc@uw.edu](mailto:iths-crc@uw.edu).

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<a href="#">Part 3: Purpose</a>	<a href="#">Part 12: UW Confidentiality Agreement</a> (Use REPORT CHANGE: Confidentiality Agreement, Personnel form instead of this form if the only change you are making is to add or remove names from an existing Confidentiality Agreement.)
<a href="#">Part 4: Procedures</a>	<a href="#">Part 13: Researchers and Research Staff</a>
<a href="#">Part 5: Populations</a>	<a href="#">Part 14: Individuals Performing Research Procedures</a>
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FOR HSD OFFICE USE ONLY

DATE RECEIVED STAMP:

- MASTER COPY
- IRB WORKING COPY
- RESEARCHER COPY
- FULL IRB REVIEW REQUIRED
- EXPEDITED REVIEW
- APPROVED
- CONDITIONAL APPROVAL
- NOTED
- DISAPPROVED
- WITHDRAWN

DORA MOD #:

DATE OF IRB ACTION:  PRINTED NAME:

IRB CHAIR OR DESIGNEE SIGNATURE:

NOTES:

### 1. Research Study & Contact Information

Full Application Title:	IRB #:	Committee:
Reduce Energy Consumption through Integrated Design: How Do Engineers Translate and Teams Synthesize Energy Modeling in Successful High Performance Building Design?	XXXX	E/J

**Lead Researcher Information (change of lead researcher requires a [modification](#))**

Name:	Title:	Position (e.g. Assistant Professor or Director):
XXX XXXXXXXX	Dr.	Associate Professor
Home Institution (or source of paycheck): <b>UW Student? Home Institution is UW.</b>		
University of Washington		
UW Department:	UW Division (Department of Medicine):	
Coonstruction Management	College of Built Environments	
UW Position or Appointment of Lead Researcher (choose the most appropriate one):		
<input checked="" type="radio"/> Regular Faculty Appointment <input type="radio"/> Research Faculty Appointment <input type="radio"/> Clinical Faculty Appointment <input checked="" type="radio"/> Faculty <input type="radio"/> Affiliate Faculty Appointment <input type="radio"/> Visiting Faculty Appointment <input type="radio"/> Dual Appointment with PNNL <input type="radio"/> Other (Describe): <input style="width: 400px;" type="text"/>		
<input type="radio"/> Student		
<input type="radio"/> UW Resident or Fellow		
<input type="radio"/> UW Administration or Staff		
<input type="radio"/> None		
Phone #:	Campus Box #:	Email:
XXX-XXX-XXXXXX	XXXXXX	XXXXXX@u.washington.edu
Other address if not at UW:		
<input style="width: 100%; height: 20px;" type="text"/>		

**Contact Person for the IRB (Change of contact person requires a [modification](#))**

Name:	Title:	Position (e.g. Assistant Professor or Director):
XXX XXXXX	Ms.	Research Assistant Professor
Home Institution (or source of paycheck):		
<input style="width: 100%; height: 20px;" type="text"/>		

University of Washington			
UW Department:		UW Division (Department of Medicine):	
Architecture		College of Built Environments	
UW Position or Appointment of IRB Contact Person (choose the most appropriate one):			
<input type="radio"/> Regular Faculty Appointment		<input checked="" type="radio"/> Research Faculty Appointment	
<input checked="" type="radio"/> Faculty		<input type="radio"/> Clinical Faculty Appointment	
<input type="radio"/> Affiliate Faculty Appointment		<input type="radio"/> Visiting Faculty Appointment	
<input type="radio"/> Other (Describe):		<input type="text"/>	
<input type="radio"/> Student			
<input type="radio"/> UW Resident or Fellow		<input type="radio"/> UW Administration or Staff	
<input type="radio"/> UW Resident or Fellow		<input type="radio"/> None	
Phone #:	Campus Box#:	Email:	Other address if not at UW:
XXXXXX	XXXX	XXXXXX@uw.edu	
<b>Name and Mailing Address for all paper-based correspondence</b> (If blank, correspondence will be directed to contact person or lead researcher if no contact person.)			
Name:	Campus Box #:	Other address if not at UW:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
<b>Name of person completing this form (if not Lead Researcher or IRB Contact)</b>			
Name:	Email:	Phone:	
<input type="text"/>	<input type="text"/>	<input type="text"/>	

END PART ONE

## 2. Reason(s) Submitted

<input checked="" type="checkbox"/>	Researcher or Sponsor Initiated Modification (Check all the types of modifications you are requesting. The requested sections will then be available in the form.):	
<input type="checkbox"/>	Part 3: Purpose	<input type="checkbox"/> Part 11: Waiver of HIPAA Authorization
<input checked="" type="checkbox"/>	Part 4: Procedures	<input type="checkbox"/> Part 12: UW Confidentiality Agreement
<input checked="" type="checkbox"/>	Part 5: Populations	<input type="checkbox"/> Part 13: Researchers and Research Staff
<input checked="" type="checkbox"/>	Part 6: Recruitment	<input type="checkbox"/> Part 14: Individuals Performing Research Procedures
<input checked="" type="checkbox"/>	Part 7: Consent/Assent	<input type="checkbox"/> Part 15: Non-UW Individuals, Organizations and Locations
<input checked="" type="checkbox"/>	Part 8: Waiver of Documentation of Consent	<input type="checkbox"/> Part 16: Investigator Brochure and/or Protocol Amendments
<input checked="" type="checkbox"/>	Part 9: Waiver of Consent or Waiver/Alteration of Elements of Consent	<input type="checkbox"/> Part 17: Funding
<input checked="" type="checkbox"/>	Part 10: Confidentiality of Research Data	<input type="checkbox"/> Part 18: Other Compliance Approval Letters/ Reports (Radiation Safety Approval, Data Safety Monitoring Reports)

END PART TWO

## 4. Procedures

**PURPOSE OF THIS SECTION:** Complete this section if you intend to change any research procedures. Procedures include (but are not limited to) developing research study instruments, changing your recruitment process, changing your consent process, requesting review of medical or other records for pre-screening or requesting records review as part of your research, changing the amount of compensation offered to subjects, adding additional surveys, questionnaires or interventions.



4.1. Summarize the proposed changes or new procedures:

We are adding a case study component to our research. We will conduct 20 case studies on already constructed high performing hospitals and other large building projects (such as universities) that have a comparable program mix to hospitals (i.e. that are mixed use with high energy intensive areas, such as laboratories).

#### Interview Component

Our case study data will consist of open-ended interviews (see "Case Study Interview Tool") with building design team members (e.g. architects, energy modelers, engineers) and owner representatives involved in the design process of each case. These interviews will involve questions about the design process (e.g. when energy modeling occurred, when project deliverables, such as energy reports were completed) and about the design team's collaboration process around the use of energy modeling and energy design decision-making. These interviews will also include prompts to determine each interviewee's attitudes towards energy modeling data (example of prompt: "Energy modeling data helps people know what design choices to make as a team", with respondents answering yes, no, and why). These interviews will help us to see how energy modeling data was used, discussed, and was a part of the design process as well as whether design team members viewed energy modeling data as constructed through collaborative processes between the modeler and other design team members, or viewed the data as a neutral fact.

Note: Some of the questions in these interviews will not be human subjects questions and instead relate to gathering information about the project's timeline, when energy modeling was conducted, when certain project deliverables were completed. Some of the interview questions are human subjects questions and relate to items such as how the teams decided to use energy modeling, how the teams collaborated together to come to an energy goal, how an energy goal was constructed, and individual attitudes towards energy modeling data.

#### Document Collection Component: Non-human subjects Data

We will also request from firms involved in the case study project documents about the project, which will include:

1. Request for proposals (RFPs)
2. Proposal from winning team for project
3. Team formation planning document (e.g. partnering agreement)
4. Pre-Design documentation
5. Schematic design documentation narrative including any sustainability sections (these include drawings from schematic design)
6. Energy planning/modeling documentation and schedules- process and final documents
7. Energy models
8. Project final documentation including sustainability narratives, rating system check-lists (such as LEED), utility incentive program documentation, or other relevant energy or sustainability documentation
9. Cost analysis - if applicable, especially related to energy systems
10. other design drawings from design development and construction documentation phases.

Within these documents we are collecting data on the following: 1) Process of energy modeling (e.g. energy model schedule, design documents related to energy design, energy design reporting, cost analysis of energy design, energy models); 2) How owner's goals were communicated in formal documents (e.g. goal stated in an RFP, energy goal statements and reports); 3) process of design and team coordination (e.g. whether teams co-located, frequency of meetings, schedule of design phases).

We would request documents about a project after they agree to take part in an interview. The data we are collecting from these documents are non-human subjects data: we are not collecting private identifiable information about subjects, only project-based information.

#### Human Subjects Protocols Summary for Case Study Procedure

In regards to our new human subject protocols for these procedures, we intend to recruit via email and conduct interviews mostly by phone or skype (but will conduct in-person interviews when possible, usually if a case study subject lives close to Seattle). Our protocols for recruitment and consent are as follows:

To conduct interviews, we will email potential participants using "Email Recruitment Script for Case Study Interviews". If the potential participant does not respond to the first email, we will recontact them using "Email Second Attempt Recruitment Script for Case Study Interviews". If they agree to the interview, we will set up a time for the interview at their convenience and conduct the interview in person if the person is located in Seattle or if there is an opportunity to travel to the location where the person works. In most cases, interviews will be conducted by phone or by skype. Prior to the interview, we will email the interview participant with an information statement, using "Information Statement for Case Studies" and at the time of the interview, we will confirm that they received the information statement and conduct oral consent using "Oral Consent Script for Case Studies". We are applying for a waiver of documentation of consent to conduct oral consent for these interviews.

4.2. Explain why the changes are being made:

We are adding this case study procedure to our study to better understand how energy modeling data and collaboration around energy modeling is integrated into building design for energy intensive projects (e.g. hospitals or buildings with a similar energy use mix to hospitals) that have already been completed and are successful in achieving their high performance energy goals (such as LEED certification). Our current data consists of ethnographic data on energy modelers and other collaborators working on projects that are many years from final construction. Our current interview data consists of interviews with experts that cover a wide range of collaborative work processes around energy modeling that do not always focus on a single successful case and only gain one perspective from a design team about a successful case. Through a case study design, we can investigate multiple perspectives on collaborative work around energy modeling on highly successful, already completed projects.

4.3. Do the changes affect any of the following processes and/or documents?

4.3.a. Recruitment process and documents, including advertisements?

- YES** Complete [Part 6](#)  
 **NO**

4.3.b. Consent process and documents?

- YES** Complete [Part 7](#)  
 **NO**

4.3.c. Records and/or research data?

- YES** Complete [Parts 10, 11 and/or 12](#), as appropriate

If you will be submitting data to the federal GWAS dbGaP data repository, complete and attach the [SUPPLEMENT: GWAS dbGaP](#)

- NO**

4.3.d. Radiation exposure?

- YES**  
 **NO**  
 **N/A**

4.3.e. Administrative/Other?

- YES**  
 **NO**

4.4. Describe the effects of these changes on the risks and/or benefits to subjects. If there are no changes in the risks or benefits, state: "None".

None.

4.5. Are you adding the use of a drug, medical device, biologic, botanical, or dietary supplement? For more information see the [SOP FDA-Regulated Research](#).

- YES**  
 **NO**

4.6. Are you adding any procedures that involve genetic research?

**Genetic research** is defined as research involving the analysis of any of the following: DNA; RNA; chromosomes; mitochondria; any or all parts of the human genome; or biomarkers such as proteins or metabolites which may be implicated in, associated with, or cosegregated with a disorder, syndrome, condition, or predisposition to disease or behavior. Usually genetic research involves the collection and/or use of human biological specimens such as blood, skin, or other tissues, nail clippings, or hair. Genetic research may also include the construction of pedigrees ("maps" of the distribution of a particular trait or condition among related individuals) or family medical histories.

- YES  
 NO

4.7. Are you adding any procedures that involve any component of the federal Department of Defense (DOD)? For more information see the [SOP Department of Defense](#).



- YES  
 NO

4.8. Are you adding any procedures that involves the federal Department of Justice (DOJ) or any of its components (such as the National Institute of Justice, or any facilities/personnel of the Bureau of Prisons)? For more information see the [SOP Department of Justice Research](#).



- YES  
 NO

4.9. Are you adding any procedures that take place under, or otherwise involve, general anesthesia?

- YES  
 NO

END PART FOUR

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## 5. Populations

5.1. Identify the changes you are requesting in subject population(s).

- 5.1.a. Add new subject population(s).  
 5.1.b. Change eligibility criteria of already-approved study population(s).  
 5.1.c. Change number of subjects approved to complete the study for an already-approved study population.  
 5.1.d. Remove existing study population(s).



5.2. Briefly describe the proposed changes in subjects population(s), and explain the reasons for this change:

We would like to be approved for 80 subjects to be added under the new subject population, "case study interview subjects". These subjects would consist of members of the design team and owner team. These subjects would only be for the case study procedure of our project.

5.2.a. Describe changes (if any) to the following for each already-approved study population, and describe the following for any new study populations being added:

Inclusion Criteria: Over 18 or under 80, participated as a member of design or owner team on a high performance hospital selected as a case study.

Exclusion Criteria: Under 18 or under 80, not a member of a design or owner team on a high performance hospital selected as a case study

Age Range: 18-80

Number of Subjects: 80

5.3. Do the changes affect the consent form(s)?

- YES  
 NO

Explain why not:

These changes do not affect the current consent forms in use for observations and interviews. We are, however, adding a new oral

consent procedure and information statement to be specifically used for this new subject population (see section 7 on consent below).

	YES	NO
5.4. Do your changes in subject population(s) involve adding any of the following federally protected populations?		
a. Pregnant women and/or fetuses	<input type="radio"/>	<input checked="" type="radio"/>
b. Neonates (newborns)	<input type="radio"/>	<input checked="" type="radio"/>
c. Minors	<input type="radio"/>	<input checked="" type="radio"/>
d. Prisoners	<input type="radio"/>	<input checked="" type="radio"/>
e. Are you removing any of the protected study populations listed above?	<input type="radio"/>	<input checked="" type="radio"/>
5.5. Do your changes in subject populations(s) involve any of the following: <ul style="list-style-type: none"><li>• Students age 21 or younger who may be participants in your research?</li><li>• Access to, or use of, personally identifiable information from student education records (current or past) from any institution or agency of education (including, but not limited to, pre-elementary, secondary, post-secondary, job training, adult education, career and technical education, special education)?</li><li>• Conducting any research procedures in an educational setting?</li></ul>	<input type="radio"/> YES	<input checked="" type="radio"/> NO
5.6. Do the changes involve adding a population of subjects (or records) from the Bureau of Prisons (BOP)? For more information see the <a href="#">SOP Department of Justice Research</a> .	<input type="radio"/> YES	<input checked="" type="radio"/> NO
5.7. Do the changes involve adding a population of subjects (or records) from the Department of Defense (DOD)? For more information see the <a href="#">SOP Department of Defense</a> .	<input type="radio"/> YES	<input checked="" type="radio"/> NO
5.8. Do the changes involve other vulnerable group(s)?	<input type="radio"/> YES	<input checked="" type="radio"/> NO



END PART FIVE

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## 6. Recruitment

6.1. Provide a general overview and context for the changes you are making to recruitment:

Our recruitment changes are only for the new case study procedure. We will be recruiting subjects via email using a new recruitment script titled, "Email Recruitment Script for Case Study Interviews" and we will use a recontact email, "Email Second Attempt Recruitment Script for Case Study Interviews" for recruitment should subjects not respond to the first email. We will wait at least one week between sending the first recruitment and the recontact email. We have added a recontact email in case the first email is missed or buried in their email inbox (many owners and workers in the architect, engineering industries receive large quantities of email a day- hence the recontacting script).

6.2. Describe the proposed changes to your recruitment process:

- If there are multiple recruitment strategies, describe each one individually;
- If there are multiple subject groups and your recruitment differs for each, describe the recruitment for each group.

The first recruitment email introduces the study to the subject and our interest in learning more about the specific building project they worked on. The follow-up email is only sent one week or more after the first email if we do not hear back from the potential subject and reiterates our interest in interviewing them about the specific building project.

6.3. Explain who will approach subjects and how this will be done to protect subjects' privacy:

A member of the research team will contact the subject via their work email. Their work email is a publicly

known email address. The research team does not discuss the identities of subjects with anyone outside of the research team.

6.4. Describe how you will minimize potential coercion or undue influence during recruitment:

Both recruitment emails state that participation is voluntary. We are contacting individuals directly and not via their workplace managers or other bosses.

6.5. Describe any changes to subjects gifts, payments, services without charge, or extra course credit, and include the value/ dollar amount, if applicable:

NA

6.6. Complete the table below for each new or revised recruitment document.

- Identify the documents that are being revised and the documents that are new.
- Attach all of the materials in the same order that you listed the documents.
- Submit 3 clean copies and 3 copies with the revisions in tracked changes (2 copies for Minimal Risk).



**Examples for Row #1** - "Type of recruitment materials" can be:

- Advertisement
- Email
- Flyer
- Letter to subjects
- Letter to colleagues
- Magazine ad or article
- Newspaper ad or article
- Oral script
- Poster
- Radio ad
- Television ad
- Website text and layout

**Examples for Row #2** - "Reason submitted" can be:

- Adding new recruitment flyer
- Deleting old recruitment letter to subjects, no longer in use
- Revising existing oral script
- Replacing existing oral script with new one

END PART SIX - Also complete the "recruitment materials" table(s)

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Recruitment materials		Table #
Row 1	Type of recruitment document or material:	1 Recruitment Email "Email Recruitment Script for Case Study Interviews", version 1.0
Row 2	Reason submitted:	To recruit for the case studies we are adding as a new procedure for our study.
Row 3	IF APPLICABLE IRB Approval Date: (most recent approval date of recruiting material being revised or replaced.)	

Recruitment materials		Table #
Row 1	Type of recruitment document or material:	2 Recontact Recruitment Email "Email Second Attempt Recruitment Script for Case Study Interviews", Version 1.0
Row 2	Reason submitted:	To be used one week from first recruitment email if we do not receive reply from first recruitment email.
Row 3	IF APPLICABLE IRB Approval Date: (most recent approval date of recruiting material being revised or replaced.)	

Add Materials Table

Remove Materials Table

## 7. Consent/Assent

7.1. Provide a general overview and context for the changes you are making: (For more information on [Consent](#) and [Consent Documentation](#), see the SOPs linked here.)

We are adding an oral consent procedure along with an information statement to be submitted to participants prior to the interview. This additional consent procedure is for **case study subjects only**. No other changes will occur to our current consent procedures for our ethnographic subjects or for our interviews with experts.

7.2. Describe the proposed changes to your consent process(es), and/or describe any new consent process(es) being added.

- If there are multiple new or revised consent processes, describe each one individually.
- Include information about who obtains consent, when, and how.

After a subject receives our recruitment email and responds that they agree to take part in the interview, we will provide them with an information statement covering our purpose, procedures, confidentiality and begin to discuss with them about our interest in collecting specific documents about their case. At the time of the interview, we will ask if they read the information statement, if they have any questions, and conduct a brief oral consent. If they have not read the information statement prior to the interview, we will provide them with another copy of the information statement and read through it with them and ask if they have any questions before asking them if they agree to take part in the study.

7.3. Do you plan to re-consent subjects?

YES

NO Explain why not:

These subjects are separate from the subjects already taking part in the ethnographic or expert interview part of our study.

7.4. Provide a complete list of all new or revised consent materials by completing the table(s) below for each new or revised consent document:

- Identify the documents that are being revised and the documents that are new.
- If you are only submitting new consent documents, write "Not applicable" in the table below, where appropriate.
- Attach all of the consent materials in the same order that you listed the documents.
- Submit 3 clean copies and 3 copies with the revisions in tracked changes. (2 copies for Minimal Risk.)



**Examples for Row #1** - "Type of consent materials" can be:

- Consent Form
- Parent Consent Form
- Parent Consent/Assent Form
- Assent Form for Age 0-6, Assent Form for Age 7-12, or Assent Form for Age 13-17
- Oral Consent Script
- Information Sheet
- Translated Consent Form
- Back-Translated Consent Form
- Consent Form approved by another IRB
- Sub-study Consent Form

**Examples for Row #2** - "Reason submitted" can be:

- Adding new consent form
- Adding new addendum to consent form
- Deleting old consent form
- Revising existing consent form to update research staff
- Replacing existing consent form that is outdated

END PART SEVEN - Also complete the "consent materials" table(s)

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Consent materials		Table #	1
Row 1	Type of consent document or material:	Information Statement for Case Studies, Version 1, to be sent to subjects via email that agree to be interviewed	
Row 2	Reason submitted:	To be submitted to subjects via email should they state that they are interested in/agree to taking part in an interview.	
Row 3	Consent Form Title:	Information Statement for Case Studies	
Row 4	Version number and/or revision date:	Version 1	
	IF APPLICABLE Consent Form Footer:		

<b>Row 5</b>		Information Statement for Case Studies, Version 1	
<b>Row 6</b>	IF APPLICABLE IRB Approval Date: (most recent approval date of consent form being revised or replaced)		

Consent materials Table # 2

<b>Row 1</b>	Type of consent document or material:	Oral Consent Script for Case Studies (to be used at beginning of interview time)	
<b>Row 2</b>	Reason submitted:	To be used at beginning of interview to confirm that they read the information statement and agree to take part in the study.	
<b>Row 3</b>	Consent Form Title:	Oral Consent Script for Case Studies	
<b>Row 4</b>	Version number and/or revision date:	Version 1	
<b>Row 5</b>	IF APPLICABLE Consent Form Footer:	Oral Consent Script for Case Studies, Version 1	
<b>Row 6</b>	IF APPLICABLE IRB Approval Date: (most recent approval date of consent form being revised or replaced)		

Add Materials Table  
Remove Materials Table

### 8. Request for Waiver of Written Documentation of Consent

A request for the waiver of the requirement for written documentation of consent means that consent will be obtained from the subjects, but there will be no verifiable written documentation signed by subjects or by subjects' legally-authorized representatives. Examples:

- Obtaining consent with an oral process (face-to-face or over the phone).
- Obtaining consent by an electronic process that does not involve a verified electronic signature. Examples: subjects provide consent with a web-based form or by email.

(For more information on [Consent](#) and [Consent Documentation](#), see the SOPs linked here.)

Complete and attach the appropriate section of the form called [SUPPLEMENT: Waiver Request, Consent Requirements](#).



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### 9. Request for Waiver of Consent or Waiver/Alteration of Elements of Consent

A request for a waiver of consent or waiver or alteration of elements of consent means that your consent process will alter, or not include, one or more of the required elements of consent, or that you will not obtain consent at all from the subjects. Example:

- For a study involving deception, you may wish to exclude the description of some aspects of the purpose and procedures.

(For more information on [Consent](#) and [Consent Documentation](#), see the SOPs linked here.)

Complete and attach the appropriate section of the form called [SUPPLEMENT: Waiver Request, Consent Requirements](#).



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## 10. Confidentiality of Research Data (including records and specimens)

Examples of when to complete Part 10:

- Change the date when the link between data and subjects' identifiers is destroyed
- Change the means of data collection, data protection, and/or storage
- Change the variables abstracted from medical records

10.1. Are you changing the date by which you will destroy the link between data and the subject's identifiers?

- YES  
 NO

10.2. Are you making any changes in how you protect the confidentiality of the research data?

- YES Describe the changes from the current IRB-approved data protection procedures:

Our expert interviews and observations from our currently approved IRB data protection have us coding identifiable information and eventually de-identifying information such as project names from documents we collect. For these case studies, we would keep information such as project names and the names of firms identifiable and in our future publications about the case studies as we want to publish these case studies to show some of the best practices and work processes that occurred on hospitals that had successful energy outcomes. All interview data would remain under our current confidentiality plan with coding our data, giving pseudonyms to subjects, and de-identifying all interview data three years after data collection completion. Items in interview that relate to non-human subjects concerns, such as a building project's timeline, schedule, budget, and so forth would be publishable (for example, "Building X" had a schedule with this timeline and modeling occurring at these points), but human subjects data related to a subject's collaboration experiences, meeting conversations, and attitudes towards modelling data would be coded, de-identified three years after data collection is complete, and not be made identifiable in publications.

- NO

10.3. Are you obtaining or using any new data (including records and specimens)?

- YES  
 NO

10.4. Will you record any direct subject identifiers as part of your new data collection activities? "Identifiers" means anything that can readily identify a subject in the context of your study and your dataset. It does not refer to the 18 types of data in health care records that are considered by HIPAA regulations to be identifying. 

- YES Explain why this is necessary:

We will need to connect the interview data on collaboration practices and experiences, project documents, and other project-related information (schedules, budgets) in order to see how collaboration practices and design processes around modeling data led to certain high energy outcomes. Without connecting our interview data using identifiers, we will not know which sets of practices and processes link to which building and its energy outcomes.

Describe how you will protect identifiable data (and/or identifiers) against breach of confidentiality, and how long you plan to maintain the link between identifiers and data and/or specimens. 

We will code identifiable data from interviews and keep a key to the code for three years after data collection is complete. We do not intend to share audio recordings (of our interview data) with anyone outside of the research team. We will keep the audio recordings for four years after transcriptions of the recordings to maintain a back-up of our coded data. Paper data is kept in a locked filing cabinet and digital data is kept on password-protected computers.

Will you retain a link between any study codes and direct identifiers after the data collection is complete?

- YES Explain why this is necessary and for how long you will retain the link/identifiers.

We will code identifiable data from interviews and keep a key to the code for three years after data collection is complete. We will keep the audio recordings

for four years after transcriptions of the recordings to maintain a back-up of our coded data. We will keep the key to the code intact for three years after data collection is complete to continue with analysis and write-up of results.

**NO**

**NO**

10.5. Who might have access to subjects' identifiable data besides the Lead Researcher (PI) and research staff? 

Only the research team and PI have access to identifiable data of subjects.

10.6. Are you now proposing to place a copy of the consent form or other study information in the subject's medical/health care record?

**YES**

**NO**

10.7. Do you anticipate using any data (information, specimens, subject contact information, etc.) from this research study for other studies in the future?

**YES**

**NO**

10.8. Are you proposing to review health care records from a health care provider, health plan, or health care clearinghouse for your research study? 

**YES**

**NO**

END PART TEN

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## 19. Attachments

- Check to make sure that all of the required attachments are included with this submission.
- Collate all of your attachments.
- Use clips, not staples, with at least one packet, so that HSD staff may easily distribute your materials to additional IRB reviewers as needed.
- If you are attaching **consent forms and materials and/or recruitment materials, provide a total of 3 clean copies of each document and a total of 3 copies of each document with the revisions in "tracked changes". (2 copies for minimal risk)**
- Unless otherwise instructed below, include 3 copies of each document. (2 copies for minimal risk)
- When possible, please order your documents as listed below.
- You should have a total of 3 complete submission "packets" with attachments included. (2 copies for minimal risk)

Explanation of Attachments (if necessary):

- Assent form(s)
- Confidentiality Agreement (**1 original ink-signed copy ONLY**)
- Consent form(s)
- Consent materials translated into a language other than English
- Consent Materials: addendum consent, information sheets, oral consent scripts
- Data collection instruments/forms
- Data safety and monitoring charter and/or report(s)
- Data Safety Monitoring Plan
- Data Use Agreement(s)
- Department of Anesthesiology Approval
- Embryonic Stem Cell Research Oversight Committee (ESCRO) approvals/letters/report
- Engagement Worksheet
- Environmental Health and Safety (EHS) approvals/letters/report
- Federal Certificate of Confidentiality or Privacy Certificate
- Grant application and title page of grant application (**1 copy ONLY**)
- Implant and Investigational Device Committee (IIDC) approvals/letters/report
- Individual Investigator Agreements
- Institutional Biosafety Committee (IBC) approvals/letters/report
- Investigator brochure (**1 copy ONLY**)
- IRB Authorization Agreements
- Literature or abstracts supporting the purpose of your research
- Material Transfer Agreement(s) (MTA)
- Oral scripts
- Other funding documentation, only if you have funding that is not a grant application/proposal
- Non-UW IRB approval letters/notifications
- Non-UW IRB approved applications
- Protocol (**1 copy ONLY**)
- Radiation Safety Applications or Radiation Safety Approval Letters (RS)
- Radioactive Drug Research Committee (RDRC) approvals/letters/report
- Recruitment - electronic materials: scripts for emails, and/or copies of web pages
- Recruitment - oral materials: scripts, radio ads
- Recruitment - written materials: flyers, brochures, newspaper ads, and/or letters
- Study instruments: surveys, questionnaires, assessment tools, tracking forms, web surveys
- SUPPLEMENT: Department of Defense Involvement
- SUPPLEMENT: Department of Justice
- SUPPLEMENT: Devices
- SUPPLEMENT: Drugs, Biologics, Botanicals
- SUPPLEMENT: Genetic Research
- SUPPLEMENT: GWAS dbGaP
- SUPPLEMENT: Protected/Vulnerable Populations
- SUPPLEMENT: Waiver Request, Consent Requirements
- SUPPLEMENT: Waiver Request, HIPAA Authorization
- Other, specify:

END ATTACHMENTS

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**Print Form**